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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,637	10/17/2003	John A. Ambrose	1059-3	1960

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EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 04/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/688,637	AMBROSE ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *1-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 October 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/17/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Claims 16-19 in the reply filed on April 11, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on October 17, 2003 has been acknowledged and is being considered by the Examiner.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: recess 52.

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "the steps of lying down the user in a supine position and elevating the user's legs at an angle substantially equal to 30 degrees" must be shown or the feature(s) canceled from the claim(s). In addition, the Examiner suggests adding a drawing (such as a flow chart or the like) depicting the method steps defined by Claims 16-19. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet,

even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. The abstract of the disclosure is objected to because of its undue length and use of legal phraseology. Correction is required. See MPEP § 608.01(b).

6. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

7. The disclosure is objected to because of the following informalities: there appears to be typographical errors at page 13, lines 8-9 and 12. At lines 8-9, the Examiner suggests changing "power source 52" to "power source 53" to remain consistent with the rest of the disclosure and

to avoid use of the same reference character to represent two separate references (see page 12 of the disclosure where "52" is used to denote "a recess"). At line 12, the Examiner suggests changing "A first notification switch is connected" to "A first notification switch 27 is connected" to include the appropriate reference character shown in Fig. 4. Appropriate correction is required.

Claim Objections

8. Claims 16-19 are objected to because of the following informalities: numerous typographical errors throughout.

As to Claim 16, the Examiner suggests changing "the symptoms are" at the second to last line of the claim to "the at least one symptom is" to avoid an antecedent basis problem (see part (f) of the claim).

As to Claims 16 and 17, the Examiner suggests changing all occurrences of "the formed ECG" to "the baseline ECG value" to avoid an antecedent basis problem.

As to Claim 18, the Examiner suggests changing the second line of the claim to read something similar to "notifying a user, upon detecting no deviation, that the data representing current bodily activity does not deviate from" to add clarity to the claim language.

As to Claim 19, the Examiner suggests changing the second line of the claim to read, "of positioning and repositioning, further comprising the steps of lying down the user in a supine" to add clarity to the claim language.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anzellini et al. (U.S. 6,339,720) (herein Anzellini). As to Claim 16, Anzellini discloses a method of determining if a user is experiencing a myocardial infarction using a CARDIOST apparatus comprising the steps of perceiving at least one symptom of myocardial infarction (such as chest pain) and positioning the apparatus on the body of a user (see Anzellini Abstract, column 5, lines 64-67, column 6, lines 1-7 and lines 43-54 and column 8, lines 39-44). Although Anzellini is silent to the use of an "activation device" to activate the apparatus, it is inherent or at least obvious to one having ordinary skill in the art at the time of the invention that the apparatus is "turned on" or "activated for use" via an on/off switch or equivalent, so as to not excessively drain the 1.5 volt alkaline disposable batteries used to power the apparatus when the apparatus is not positioned on the body of a user for myocardial infarction detection.

Anzellini discloses that once the apparatus is positioned on the body of the user, after the user has experienced at least one symptom of myocardial infarction (such as chest pain), data representing current bodily activity (electrocardiographic data) is recorded and compared to data representing a baseline ECG value for determining if the current bodily activity deviates from the data representing the baseline ECG value by a predetermined deviation value (i.e. number of milimeters or number of microvolts) and notifying a user vial lights 18-20 or alarm 21, upon

detecting the deviation, that the at least one symptom is indicative of myocardial infarction. It is inherent that the microcontroller unit 17 uses memory to store the baseline ECG value used for comparison (see Anzellini column 6, lines 5-67, column 7, lines 1-9, column 9, lines 18-67 and column 10, lines 1-16).

Anzellini discloses the claimed invention as discussed above but does not expressly discloses that prior to perceiving at least one symptom of myocardial infarction, the apparatus is used to establish the data representing the baseline ECG value from the plurality of electrodes positioned on the user. It would have been an obvious matter of design choice to a person having ordinary skill in the art to modify the method as taught by Anzellini with such steps to establish a baseline ECG, because Applicant has not disclosed that having a baseline ECG value associated with the user of the apparatus provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the "universal baseline ECG value" as taught by Anzellini, because it provides a method and apparatus for detecting myocardial infarction that is capable of being used with any person/patient/user and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Anzellini.

Therefore, it would have been an obvious matter of design choice to modify Anzellini to obtain the invention as specified in the claim(s).

11. As to Claim 17, Anzellini discloses that the step of comparing includes comparing an ST-segment of the data representing current bodily activity with an ST-segment of the data representing the baseline ECG value (see Anzellini Figs. 2A-2G, column 6, lines 55-67, column 7, lines 1-9, column 9, lines 18-67 and column 10, lines 1-16).

12. As to Claim 18, Anzellini discloses that the method further comprises the step of notifying a user (via green alarm 18), upon detecting no deviation, that the data representing the current bodily activity does not deviate from the data representing the formed ECG by a predetermined deviation value (see Anzellini Fig. 3B and column 9, lines 18-34).

13. As to Claim 19, Anzellini discloses the claimed invention except for the steps further comprising lying the patient down in a supine position and elevating the user's legs. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Anzellini, to include steps further comprising lying the patient down in a supine position and elevating the user's legs since it was known in the art that lying a patient down during a suspected myocardial infarction decreases the amount of oxygen being used by the body's extremities and may prolong the amount of time the patient receives oxygen to vital organs (such as the heart itself and the brain). In addition, it was known in the art that lying a patient down and elevating the patient's legs during a suspected myocardial infarction forces blood located in the extremities back to the heart quicker than would be possible without elevating the legs, because when a patient is experiencing a myocardial infarction it is beating irregularly and in an uncoordinated fashion decreasing its ability to circulate blood through the body. The modified Anzellini reference discloses the claimed invention as discussed above except it is not specified that the legs be elevated at an angle substantially equal to 30 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to elevate the legs at an angle substantially equal to 30 degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bible (U.S. 5,181,519) appears to anticipate or at least render obvious over Claims 16-19.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica L. Reidel 04/25/06
Examiner
Art Unit 3766

Robert E. Pezzuto
Supervisory Patent Examiner
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